

IN THE UNITED STATES DISTRICT COURT  
 FOR THE NORTHERN DISTRICT OF TEXAS  
 AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC	)	2:22-CV-223-Z
MEDICINE, et al.,	)	
Plaintiffs,	)	
	)	
	)	
VS.	)	AMARILLO, TEXAS
	)	
	)	
U.S. FOOD AND DRUG	)	
ADMINISTRATION, et al.,	)	
Defendants.	)	March 10, 2023

TRANSCRIPT OF TELEPHONIC STATUS CONFERENCE  
 BEFORE THE HONORABLE MATTHEW J. KACSMARYK  
 UNITED STATES DISTRICT JUDGE

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23 Proceedings reported by mechanical stenography and  
24 transcript produced by computer.  
25

1 TELEPHONIC STATUS CONFERENCE - MARCH 10, 2023

2 P R O C E E D I N G S

3 THE COURT: The Court calls Civil Action Number  
4 2:22-CV-223-Z, Alliance for Hippocratic Medicine versus U.S.  
5 Food and Drug Administration for status conference on the  
6 pending motion for preliminary injunction in ECF Number 6  
7 alongside the responsive documents filed by the Defendants.

8 This status conference is on the record with Northern  
9 District of Texas court reporter Todd Anderson. He is assigned  
10 to Chief Judge Godbey but has graciously agreed to cover this  
11 proceeding.

12 Mr. Anderson, are you present and transcribing?

13 THE REPORTER: I am, Judge. Good afternoon.

14 THE COURT: Okay. So at this point, I'll identify  
15 the attorneys who should be on the line and the parties they  
16 represent.

17 By order dated March 8th, ECF Number 124, this Court  
18 instructed the parties to identify to the courtroom deputy on  
19 or before 10:00 a.m. today the lead and associate counsel  
20 participating in this status conference.

21 The courtroom deputy received the following names.  
22 These persons should respond present when I call his or her  
23 name.

24 For the Plaintiffs, Erik Baptist?

25 MR. BAPTIST: Present.

1 THE COURT: And Erin Hawley?

2 MS. HAWLEY: Present.

3 THE COURT: For the Defendants HHS and FDA, Noah  
4 Katzen?

5 MR. KATZEN: Present.

6 THE COURT: Julie Straus Harris?

7 MS. STRAUS HARRIS: Present.

8 THE COURT: And Kate Talmor?

9 MS. TALMOR: Present.

10 THE COURT: And for Defendant Intervenor, Jessica  
11 Ellsworth?

12 MS. ELLSWORTH: Present.

13 THE COURT: Catherine Stetson?

14 MS. STETSON: Present.

15 THE COURT: Kaitlyn Golden?

16 MS. GOLDEN: Present.

17 THE COURT: And Ryan Patrick Brown, who is listed as  
18 local counsel?

19 MR. BROWN: Present.

20 THE COURT: Finally, in the interest of full  
21 disclosure and for record purposes, the courtroom deputy, law  
22 clerks, and interns are physically present for this status  
23 conference, but they're only in an observer status and will not  
24 audibly participate, but I wanted the parties and attorneys to  
25 be aware of their presence.

1           So the purpose of this status conference is to  
2           announce the hearing that will be set in the pending motion for  
3           preliminary injunction. Again this is ECF Number 6.

4           The Court will hold a hearing on Plaintiff's pending  
5           motion for preliminary injunction at 9:30 a.m. central daylight  
6           time on Wednesday, March 15, 2023.

7           The hearing will take place in the J. Marvin Jones  
8           Federal Building and Mary Lou Robinson United States Courthouse  
9           located at 205 Southeast 5th Avenue, Amarillo, Texas  
10          79101-1559.

11          Counsel for all parties involved are expected to be  
12          present, and I am instructing now the parties to be prepared to  
13          discuss, explain, and argue any issue raised by the briefing,  
14          including, but not limited to, the following topics, which may  
15          serve as an outline for your hearing practice.

16          First: Plaintiff's standing to sue, including  
17          associational, organizational, zone of interest standing.

18          Judicial reviewability, including the Reopening  
19          Doctrine, Heckler v. Chaney, specifically the committed to  
20          agency discretion by law, neither briefed by the parties.

21          Exhaustion of Comstock Act claims and arguments,  
22          including any exceptions that might apply, including futility  
23          or that agency action may result in individual injustice or  
24          that it is contrary to important public policy. And then in  
25          that category of exhaustion and the Comstock Act whether this

1 issue is raised with sufficient clarity by the LLC memorandum  
2 provided by the Department of Justice.

3 Next, Number 3, Subpart H, including the history of  
4 texts and applicability and the FDA's implementation vis-à-vis  
5 the 2000 approval.

6 4. Agency decisionmaking, including restrictions,  
7 labeling, elements and conditions arising under the FFDCA,  
8 PREA, FDAAA, and elements to assure safe use under 21 U.S.  
9 Code, Section 355-1.

10 Fifth: Irreparable harm, including third-party  
11 issues of any APA deference standards that may apply and public  
12 interest in balancing.

13 Sixth: The public interest prong, specifically  
14 Plaintiff's stated theories relevant to public health, police  
15 power, and Defendant's stated theories relevant to FDA  
16 policymaking.

17 And then finally, remedies. Any arguments on what  
18 this Court may do as fashioning a remedy, withdrawal and/or  
19 suspension under Section 35 -- I'm sorry -- Section 355(e) and  
20 (f), and then any arguments on what the APA provides in terms  
21 of setting aside or vacating. So be prepared to discuss what  
22 remedies you propose should this Court grant relief to the  
23 movants.

24 Now, as far as format, I previously served as an  
25 appellate division AUSA, and I modeled my longer hearings on

1 the typical Fifth Circuit pattern for argument. Rest assured  
2 you're not going to be given just 20 minutes, but it will  
3 follow that same pattern. The appellant goes first, the  
4 appellee goes second, and then the appellant receives set aside  
5 full rebuttal if they elect to do so.

6 So here that would mean Plaintiffs are allocated two  
7 hours but may reserve time for rebuttal. And just be careful  
8 to announce that time to the Court.

9 The Court will then recess for 15 minutes to allow  
10 all Defendants time to reconfigure the courtroom as necessary,  
11 and the Defendants are allocated two hours with no rebuttal  
12 time available.

13 And then Plaintiffs will conclude the hearing with  
14 any rebuttal time reserved.

15 So it will follow a typical Fifth Circuit pattern  
16 with the movant beginning and holding back a portion if  
17 necessary for rebuttal, the respondent then having the full two  
18 hours, and then whatever rebuttal is reserved.

19 Plaintiff and Defendants shall determine how much  
20 time will be allocated among each individual party and each  
21 attorney, but I'll caution you that you should sequence your  
22 attorney time to avoid alternating counsel at the microphone.  
23 I don't have a one-party/one-attorney rule, but I do ask that  
24 you don't force the Court to play whack-a-mole with the various  
25 attorneys hopping up and down at the podium.

1           So I do allow multiple attorneys to argue different  
2 portions of the hearing. I just ask that you be disciplined  
3 about the sequence. So as you structure your outline and  
4 argument that different attorneys are going to argue different  
5 issues or matters, just be careful the sequence of those in a  
6 way that it doesn't disrupt decorum and the pace of the  
7 hearing.

8           So here this allocation of time is based on the  
9 Court's review of the Intervenor Defendant response along with  
10 Plaintiff's motion and Defendant's briefing in this case. The  
11 Court finds that Defendants and the Intervenor Defendant have  
12 substantially similar arguments, and for that reason the Court  
13 is instructing the Defendants to allocate time between  
14 Defendants FDA and HHS and the Defendant Intervenor. So the  
15 parties may allocate that time as they wish.

16           I'll also note for the record here Plaintiffs also  
17 have multiple parties involved. If they intend to present  
18 counsel for particular plaintiffs, they may do so.

19           So here the Plaintiff and Defendants are instructed  
20 to allocate their time. Accordingly, you both have two hours  
21 in the sequence the Court described.

22           Now, regarding housekeeping for the attorneys in this  
23 case, all of which have not appeared before this Court except  
24 for Mr. Brown. It's important to bring your bar card or any  
25 government identification when you enter the courthouse. This

1 will allow you to proceed through security with electronic  
2 devices. So we have strict rules about the persons in the  
3 court space allowed to use technology like laptops, iPads, and  
4 cell phones.

5 If you have your bar card or you have your DOJ  
6 credentials or anything like a government ID, you'll be allowed  
7 to proceed with your electronic devices. All other persons  
8 will be asked to leave those devices outside the courtroom.

9 So be careful to have that bar card or form of  
10 identification noting you as the counsel of record, and you  
11 will be allowed to bring your laptop and other devices.

12 I'll also instruct that by 10:00 a.m. CST Tuesday,  
13 March 14, 2023, all attorneys seeking to present at the hearing  
14 that they submit their business cards to my courtroom deputy  
15 for court reporter purposes and any spellings.

16 I'll also instruct the parties on or before 10:00  
17 a.m. CST Tuesday, March 14, 2023, to submit a term list.

18 I know that we have many abbreviated statutes and  
19 regulations. We also have various jurisprudential terms that  
20 could be potentially confusing to the court reporter. I'll  
21 just instruct the parties to separately submit their intended  
22 term list. And this should include things like FFDCA, PREA, if  
23 that's how you intend to pronounce it, P-R-E-A, those  
24 abbreviations and those case-specific terms that could be  
25 potentially confusing to the court reporter transcribing the

1 case.

2 So on or before 10:00 a.m. on Tuesday, please have  
3 those submitted to the Court, and we will refer those to the  
4 court reporter.

5 And, also, for clarity purposes and to preserve a  
6 good record on appeal, when you're citing parts of the record,  
7 I will instruct the parties to use the ECF page numbering at  
8 the top of the page, which may or may not correspond to the  
9 original pagination of the briefing.

10 So sometimes it could be confusing for an appellate  
11 attorney reviewing an ROA when people are using different  
12 paginations, so here I'll just ask that the parties have some  
13 discipline in using the pagination of the ECF page numbering.  
14 So that should be the blue numbers at the top and the watermark  
15 that the court places.

16 And if you are citing any of the various appendices,  
17 I'll ask that if you do intend to cite the appendices of  
18 Plaintiff's complaint -- and, again, that's ECF Number 1 --  
19 note that various versions of these appendices were double  
20 marked by the ECF system. So if you are going to cite to any  
21 appendices attached to Plaintiff's complaint that you use the  
22 one that isn't double marked. And I believe that was the  
23 original attachment.

24 So some of the documents have been filed in multiple  
25 pleadings. I'll just ask to use some discipline in using the

1 ECF marks that were not double and triple marked. That will  
2 avoid some confusion.

3 Now, importantly, I do allow PowerPoint  
4 presentations, courtroom technology. My predecessor was  
5 adamantly opposed to courtroom technology, but we have changed  
6 those rules. The local rules are no longer in play. I just  
7 ask that you work diligently with our courtroom deputy and IT  
8 support staff to pre-clear your equipment.

9 And so the Court orders that on or before 10:00 a.m.  
10 central standard time on Tuesday, March 14, 2023, that you  
11 submit with detail the IT equipment you intend to use. And you  
12 should not assume that the satellite division has the same  
13 level of IT support that you might expect in the Dallas  
14 Division or the Fort Worth Division. So it's critical to your  
15 presentation that you communicate effectively to our IT staff  
16 the type of device that you want to use. Laptops, iPads, any  
17 USB, hardwire connections that you intend to use, if you can  
18 give operating systems, things like that. Just give as much  
19 detail as will assist our IT support to make sure when you  
20 arrive you can be ready to go at the start of the hearing.

21 So I'll permit the parties to arrive as early as 8:00  
22 to coordinate with IT support to check their connectivity.  
23 Any materials that you want to present by visual aid or ELMO or  
24 any other device you can test-drive that equipment at 8:00 the  
25 morning of the hearing.

1           And because of limited security resources and  
2           staffing, I will ask that the parties avoid further publicizing  
3           the date of the hearing. This is not a gag order but just a  
4           request for courtesy given the death threats and harassing  
5           phone calls and voicemails that this division has received. We  
6           want a fluid hearing with all parties being heard. I think  
7           less advertisement of this hearing is better.

8           So I'm not ordering under any gag order doctrine that  
9           you are gagged. I'm just requesting it as a courtesy to the  
10          Court and court staff.

11          So other elements of this case have brought a barrage  
12          of death threats and protesters and the rest. I don't want  
13          that to disrupt your presentation to the Court.

14          So we will have standard security protocols in place,  
15          but I'll just ask as a courtesy that you not further advertise  
16          or Tweet any of the details of this hearing so that all parties  
17          can be heard and we don't have any unnecessary circus-like  
18          atmosphere of what should be more of an appellate-style  
19          proceeding.

20          So with that, I know you were taking notes. Are  
21          there any questions from the Plaintiffs? And I'll ask that you  
22          identify yourself by name if you're going to speak on behalf of  
23          the Plaintiffs.

24          MR. BAPTIST: Your Honor, this is Erik Baptist on  
25          behalf of Plaintiffs. I have no questions.

1 THE COURT: Okay. And for Defendant HHS and FDA? I  
2 understand that there are some people in professional  
3 capacities. I'm just using HHS and FDA as placeholders for the  
4 entire signature block.

5 So anything from Defendants HHS and FDA?

6 MS. STRAUS HARRIS: Yes, Your Honor. This is Julie  
7 Straus Harris with the Department of Justice for the  
8 Defendants.

9 Just two matters. One, will the parties be  
10 provided -- we've been taking notes, but will the parties be  
11 provided with any written copy of these instructions separate  
12 from our notes?

13 THE COURT: There will be an order setting the  
14 hearing on Tuesday. So I will memorialize these instructions,  
15 deadlines, and the rest in an order that will file sometime  
16 Tuesday.

17 But if you have questions about the particulars, you  
18 should probably ask them now, because I don't want to have any  
19 confusion that late in the game.

20 MS. STRAUS HARRIS: Thank you, Your Honor. I don't  
21 think we have any specific questions about those instructions  
22 right now.

23 The order that you just indicated would be put on the  
24 docket on Tuesday, would that -- will that order be publicly  
25 available on the docket?

1 THE COURT: It will. It will. But to minimize some  
2 of the unnecessary death threats and voicemails and harassment  
3 that this division has received from the start of the case,  
4 we're going to post that later in the day. So it may even be  
5 after business hours, but that will be publicly filed. That  
6 will be available on ECF and PACER, and it will memorialize the  
7 instructions given today.

8 MS. STRAUS HARRIS: Thank you very much for that  
9 clarification.

10 And will the hearing itself be open to the public?

11 THE COURT: Yes.

12 MS. STRAUS HARRIS: Thank you, Your Honor.

13 THE COURT: Yeah. So we have court -- the first  
14 floor courtroom has a gallery. It's the primary courtroom for  
15 the division. I am reserving the first row for the parties.  
16 That could include paralegal support, any experts that you may  
17 bring. Anybody who is not at the microphone may assemble in  
18 that first row. There is sort of a movant's side and a  
19 respondent's side of the courtroom.

20 And I have actually tried a case in that court space  
21 as an AUSA, and it was a big national security FISA case. And  
22 we had to use those first rows for all sorts of FBI personnel  
23 for that. So I don't know how many attorneys and support staff  
24 that you're bringing with you, but I will reserve the first row  
25 for each side, so you can rely on that spacing.

1 Everything beyond that first row will be general  
2 audience seating. We have all the rules in place for decorum  
3 and courtroom technology and the rest.

4 There will be numbered seating. So it's a little bit  
5 similar to the way we do voir dire. We got used to this sort  
6 of spacing during COVID, and we've continued to use a numbering  
7 system for seats assigned. So anybody attending the hearing in  
8 a general public capacity will be assigned a number, and  
9 they're allowed to remain present for the hearing at that  
10 point, you know, subject to all the rules about disruption of  
11 decorum.

12 I will note that once those seats are filled, the  
13 courtroom will be closed at that point.

14 If any media are in attendance, they can do the  
15 shuttle system where, you know, members of the same newspaper  
16 or media outlet might use the same number, but once the seats  
17 are filled, the seats are filled.

18 I have a magistrate judge who uses the second floor  
19 for primarily criminal matters on the Friday docket, initial  
20 appearances, things like that. So we have to be -- we have to  
21 be judicious in our use of space. But that is what any member  
22 of general public should expect.

23 MS. STRAUS HARRIS: Thank you, Your Honor.

24 What you just said makes one additional question from  
25 me, which is that you referred to experts that any party may

1 bring. Will the Court entertain testimony at the hearing?

2 THE COURT: No. This is just for -- this is just for  
3 argument. If it's not an attachment and it's not part of the  
4 paper in this case, it's not allowed at the hearing. You may  
5 make reference to that, and you may have personnel who serve as  
6 support staff or the rest. I only use the word "expert"  
7 because I know there could be non-attorney personnel at FDA or  
8 HHS who want to sit through the hearing even in an observer  
9 capacity.

10 So I didn't want to prejudice you in any way in  
11 limiting my definition of trial participant to just attorneys  
12 and paralegal support. So I said expert because I anticipated  
13 that you might have some medical professionals or whoever who  
14 want to observe and even pass notes, but we're not taking  
15 testimony.

16 MS. STRAUS HARRIS: Thank you, Your Honor.

17 THE COURT: Okay. And any additional questions from  
18 Defendants HHS and FDA?

19 MS. STRAUS HARRIS: Not at this time, Your Honor.  
20 Thank you.

21 THE COURT: So from Defendant Intervenor, any  
22 questions?

23 MS. ELLSWORTH: Thank you, Your Honor. This is  
24 Jessica Ellsworth. I just have one question having not been in  
25 your courtroom, which is, is there a separate counsel table in

1 front of the first row that you were describing? And if so,  
2 can you tell us how many seats are there so we can think about  
3 that?

4 THE COURT: Yes. And if you want to discuss  
5 courtroom configuration, Ryan Patrick Brown, your local  
6 counsel, is a good resource. He has been in my court --

7 MS. ELLSWORTH: Certainly.

8 THE COURT: -- almost weekly on criminal docket  
9 matters.

10 So there are two tables that can easily sit -- seat  
11 two with -- you know, with some potential claustrophobia three  
12 or four. So in a typical criminal matter, we'll have two AUSAs  
13 and a case agent seated at the table comfortably. You could  
14 feasibly do four with some tight spacing.

15 Immediately behind counsel table -- and by the way,  
16 there are two microphones at these tables. Immediately behind  
17 those tables are a row of swivel chairs that are typically used  
18 by an FBI agent or any investigators in a criminal case. I'll  
19 allow you to use those for any attorneys, sort of an overflow  
20 section for counsel.

21 And then I anticipate anybody else who's part of your  
22 team that, you know, aren't likely to be at the microphone can  
23 then occupy that first row.

24 So having tried a case in that courtroom, that's kind  
25 of my vision for how we'll do staffing and seating.

1           So the Defendants will need to decide and also the  
2           Plaintiffs how they want to allocate those two to three seats  
3           and then the chairs immediately behind those and then the row  
4           behind that. So that's kind of the layout. And bigger cases  
5           can get tight.

6           The court space is horizontally wide but not  
7           vertically deep. So this is different than the second floor  
8           courtroom, which is a refurbished post office, which is very,  
9           very deep with lots of gallery space but narrow for attorneys.  
10          So I determined that this was a better courtroom in a case that  
11          may involve more attorneys and less gallery.

12                 MS. ELLSWORTH: Thank you very much, Your Honor.

13                 THE COURT: So in thinking deep versus wide, we are  
14          in the courtroom that is wide, which will allow for a lot of  
15          courtroom technology. We do -- thanks to the CARES Act, we do  
16          have a large video screen that can project PowerPoints,  
17          exhibits, things of that sort. We also have an ELMO that's  
18          connected to that screen. It's a better space for the  
19          attorneys, but it doesn't have as much gallery space for the  
20          general public. So it is wide but not deep.

21                 Any additional questions from the Defendant  
22          Intervenor?

23                 MS. ELLSWORTH: No, Your Honor. Thank you very much.

24                 THE COURT: Okay. With that, you can expect an order  
25          memorializing these instructions to issue later on Tuesday.

1 And if you need to double-check, check your notes for any times  
2 or instructions. You can always use the NDTX portal on the  
3 left side or contact my courtroom deputy. But I will warn all  
4 involved that there's only one person in this courthouse you  
5 can't piss off, and it's not me, it's my courtroom deputy. So  
6 please be judicious in reaching out to the courtroom deputy.

7 So with that, this matter is adjourned, and we're off  
8 the record. And you're ordered to reappear for a hearing on  
9 Wednesday at the appointed date and time.

10 (Hearing adjourned)

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1 I, TODD ANDERSON, United States Court Reporter for the  
2 United States District Court in and for the Northern District  
3 of Texas, Dallas Division, hereby certify that the above and  
4 foregoing contains a true and correct transcription of the  
5 proceedings in the above entitled and numbered cause.

6 WITNESS MY HAND on this 14th day of March, 2023.

7  
8  
9 /s/Todd Anderson

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